

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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ABBOTT GMBH & CO., KG, ABBOTT  
BIORESEARCH CENTER, INC., ABBOTT  
BIOTECHNOLOGY, LTD.

Plaintiffs,

v.

CENTOCOR ORTHO BIOTECH, INC.,  
CENTOCOR BIOLOGICS, LLC.

Defendant.

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C.A. No. 4:09-CV-11340 (FDS)

JURY TRIAL DEMANDED

**ABBOTT'S OPPOSITION TO CENTOCOR'S MOTION  
FOR LEAVE TO FILE AMENDED PRELIMINARY INVALIDITY AND NON-  
INFRINGEMENT CONTENTIONS**

Plaintiffs Abbott GmbH & Co., KG, Abbott Bioresearch Center, Inc., and Abbott Biotechnology Ltd. (collectively “Abbott”) hereby submit their Opposition to Defendants Centocor Ortho Biotech, Inc.’s and Centocor Biologics LLC’s (collectively “Centocor’s”) Motion for Leave to File Amended Preliminary Invalidity and Non-Infringement Contentions (“Motion to Amend Contentions”), filed April 15, 2011,<sup>1</sup> Dkt. No. 155.

## **I. BACKGROUND**

Centocor’s Motion to Amend Contentions consists of a conclusory two-sentence request to amend Centocor’s Contentions based solely on the assertion “that there is good cause for amending its invalidity contentions to account for the Court’s March 17, 2011 claim construction order in this case.” However, the Initial Scheduling Order in operation in this matter states that after October 8, 2010 (30 days before the Markman hearing), Centocor may amend or supplement its preliminary invalidity and non-infringement contentions “only by leave of court, for good cause shown” unless the amendment or supplementation is in response to an amendment or supplementation by Abbott. (*See* Initial Scheduling Order (Mar. 2, 2010), Dkt. No. 44 (“Scheduling Order”) at ¶ 1(c).) Local Rule 16.6(D)(1) (which has not been incorporated into the Scheduling Order in this matter) does permit amendment or supplementation of contentions following the Court’s claim construction ruling, but *only if* that amendment or supplementation is “necessary” in light of the claim construction ruling:

*If necessary*, the parties may amend their preliminary infringement/non-infringement and invalidity disclosures, noting whether any infringement or invalidity contentions are withdrawn, within [30] days after the Court’s ruling on the claim construction.

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<sup>1</sup> Centocor filed its Motion to Amend Contentions on April 14, 2011, at 9:37 p.m. EDT, deeming it filed on April 15, 2011, pursuant to Local Rule 5.4(D).

Not only has Centocor failed to show the necessity for amending its Contentions as a result of the Court's claim construction ruling, but a review of the proposed amendments reveals that at least some of these amendments have nothing to do with the ruling, and are, rather, an improper attempt by Centocor to circumvent the Scheduling Order and Local Rules to expand its invalidity and non-infringement positions.

## **II. ARGUMENT**

There are at least two categories of proposed amendments to Centocor's Contentions that, on their face, have no relation to this Court's claim construction ruling.<sup>2</sup>

*First*, Centocor seeks to amend its Contentions to assert a non-infringement position based on Centocor's proposed construction of the term "human antibody." Specifically, Centocor seeks to include the following statement in its Contentions, which was not part of the last set of Contentions Centocor served on Abbott on October 8, 2010:

[T]he accused product does not comprise a human antibody as set forth in all the asserted claims of the 128 and 485 patents, because it does not have variable and constant regions corresponding to human germline immunoglobulin sequences as described by Kabat et al. (1991) *Sequences of proteins of Immunological Interest, Fifth Edition*, U.S. Department of Health and Human Services, NIH Publication No. 91-3242) and has more than twenty positions replaced with amino acid residues which are not part of the human germline immunoglobulin sequence.

(Ex. 1 at 71-72.) Centocor previously sought to add this statement to its Contentions as part of its Motion for Leave to File Amended Preliminary Invalidity and Non-Infringement Contentions, filed February 23, 2011, Dkt. No. 122. Abbott opposed this motion to the extent Centocor

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<sup>2</sup> Attached hereto as Exhibit 1 is a blackline comparison between Centocor's Contentions dated Oct. 8, 2010, and Centocor's proposed Amended and Supplemented Contentions, which are attached as Exhibit A to Centocor's Motion to Amend Contentions.

sought to add this non-infringement position,<sup>3</sup> and the Court took the motion “under advisement” pending its decision on the claim construction of the term human antibody. (*See* Electronic Order of March 16, 2011; Abbott’s Opposition in Part to Centocor’s Motion for Leave to File Amended Preliminary Invalidity and Non-Infringement Contentions, dated Mar. 8, 2011, Dkt. No. 133.) That term has not yet been construed by the Court, and there is no basis for Centocor to seek to include this human antibody position in its latest request to amend its Contentions.

*Second*, Centocor seeks to amend its position on indefiniteness – specifically, that the claims of the asserted patents are invalid because they recite “biological properties, including IC<sub>50</sub>’s, the values of which depend on the testing methods and conditions used” – to also include the following statement:

For example, the IC<sub>50</sub> values depend on the amount of interleukin used in the assays. As an additional example, the IC<sub>50</sub> values depend on the type of interleukin used in the assay. As an additional example, the IC<sub>50</sub> values depend on whether cells are used in the assay and, if so, what type or batch of cells are used. As an additional example, the IC<sub>50</sub> values in a receptor binding assay depend on whether the receptors in the assay are located on the surface of a cell or on the surface of a laboratory dish. As an additional example, the IC<sub>50</sub> values depend on whether one or both subunits of the IL-12 receptor are present in the assay.

(*See* Ex. 1 at 68.) Nowhere in its claim construction order did this Court make any rulings that would now necessitate Centocor to list alleged examples of ways in which IC<sub>50</sub> values depend on testing methods and conditions. Indeed, the only references to IC<sub>50</sub> values in the order are 1) with regard to the claim terms themselves, which recite specific infringing IC<sub>50</sub> values, and 2) in the context of explaining what an IC<sub>50</sub> value is:

Affinity may be assessed using several kinds of “assays,” or tests. One measure of effectiveness used during these tests is the concentration of an antibody required

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<sup>3</sup> Abbott did not oppose Centocor’s motion to the extent it sought leave to add the reference Tomlinson et al., J. Mol. Biol. 256:813 (1996), and it continues to not oppose the addition of this reference.

to cut the biological activity of the antigen in half. This number is known as the “IC<sub>50</sub>” for that antibody.

Amended Memorandum and Order on Claim Construction (Mar. 17, 2011), Dkt. No. 139, 3-4, 16, 26-27. These references to the claims and to a basic understanding of what IC<sub>50</sub> values are do not provide any new information that Centocor did not have prior to the claim construction ruling. Centocor now seeks to include this information in its Contentions in a belated and improper attempt to bolster its invalidity position, and this should not be permitted.

With regard to the remaining amendments Centocor seeks to make to its Contentions, Centocor has not met its burden of showing good cause or necessity because Centocor has not even attempted to explain which amendments it seeks to make and why these amendments are necessary in light of the Court’s claim construction ruling. Specifically, Centocor seeks to include 15 new reference combinations (in addition to the Tomlinson reference, to which Abbott does not object, as explained *supra* in footnote 3) in support of its obviousness assertions. (Ex. 1 at 24-36.) It also seeks to add fourteen separate reference citations that identify which portion of each reference purportedly renders obvious each asserted claim of the patents-in-suit. (*Id.* at 37-56.) Finally, Centocor seeks to add six references to the portion of its Contentions that assert that the patents-in-suit are anticipated by a prior invention. (*Id.* at 67.) Centocor’s motion provides absolutely no information to explain how the Court’s claim construction ruling necessitates these amendments. Centocor should not be permitted to place the burden of ascertaining the potential necessity of these amendments on Abbott.

## **CONCLUSION**

For the foregoing reasons, Abbott respectfully requests that Centocor’s Motion for Leave to File Amended Preliminary Invalidity and Non-Infringement Contentions be denied.

Respectfully Submitted,

Dated: April 25, 2011

/s/ Robert J. Gunther, Jr.

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### **CERTIFICATE OF SERVICE**

I certify that, on April 25, 2011, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/Robert J. Gunther, Jr. \_\_\_\_\_